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## SYSTEM FOR X-RAY IRRADIATION OF BLOOD

### BACKGROUND OF THE INVENTION:

5 The present application claims the priority date of  
U.S. Provisional Patent Application Serial No.60/098,884  
filed on 09/02/98 in the name of Randol E. Kirk, the  
inventor herein.

10 X-Ray irradiation of blood plasma is one of the methods  
sanctioned by the U.S. Food and Drug Administration for  
providing a product which diminishes the chance of  
transfusion-induced diseases. For this purpose, the  
radiation dose and dose distributions that may occur from

X-ray sources must be controlled accurately for meeting regulatory requirements.

5 X-ray irradiation for sterilization has several advantages over gamma ray irradiation, electron beam application and other types of blood purification. First, X-rays can be accurately controlled in application and secondly, equipment for providing the X-rays is relatively safe, and also, the equipment for providing the X-rays is comparatively inexpensive as compared to the other types of blood purification.

10 SUMMARY OF INVENTION:

15 The inventive blood irradiator provides a uniform dose of X-ray beam irradiation for a blood plasma contained in a blood transfusion bag. In one embodiment, the bag is placed in a selected cannister for receiving the X-ray beam, and the system includes two X-ray tubes positioned to irradiate the bag from opposite sides to provide a uniform radiation to the blood in the bag.

20 The foregoing features and advantages of the present invention will be apparent from the following more particular description of the invention. The accompanying drawings, listed herein below, are useful in explaining the

invention.

Fig. 1 is a view showing a schematic of a basic structure of the inventive system;

Fig. 2 is a view showing a blood transfusion bag and the cannister for receiving the bag;

Fig. 3 is a sketch showing the positioning of the X-ray tubes relative to the cannister of one embodiment of the invention and is useful in explaining the apparatus for irradiating the bags;

Fig. 4 is a sketch of an embodiment of the invention using a single source of irradiation;

Fig. 5 is an embodiment of the invention wherein the machine 12 includes a sliding door for closing the irradiation chamber; and

Fig. 6 shows an embodiment of the invention having hinged door for closing the irradiation chamber.

#### DESCRIPTION OF THE INVENTION:

The present invention provides an apparatus for insuring dose uniformity for a blood contained in a transfusion bag that receives X-ray beam radiation from X-ray tubes.

Referring to Figs. 1-3, the inventive X-ray system

comprises a suitably shielded apparatus or machine 12, which may be portable. The machine 12 includes a first X-ray tube or source 15 which is oriented to provide a beam of X-rays downwardly, indicated by the dotted lines 16, to a chamber 19 which is adapted to receive a cannister or container 18 for the blood plasma bag.

The cannister 18 has an oval shaped interior for receiving the transfusion bag 20, and includes a cover or top 21, see Fig. 2. The cannister 18 is dimensioned and positioned to maintain the blood plasma transfusion bag 20 at a precise distance and position relative to the X-ray tube 15, see Fig. 3. Cover 21 controls the depth or thickness of the blood bag 20 within cannister 18. Importantly, the cannister 18 is dimensioned to receive the cover 21 to maintain the thickness of 4cm throughout the bag. The system includes suitable radiation security switches so that X-ray exposures can be initiated only when all the radiation doors have been closed, as is known.

In the embodiment shown, X-ray tube 15 has an output of 160 kV and the X-ray beam output port of tube 15 is designed to provide a relatively wide X-ray beam of 40-50 degrees in order to provide a beam with a sufficiently large diameter to fully cover the cannister 18 and the included bag 20, as

will be discussed. The X-ray tube is positioned relatively close, that is 23cm, from the upper surface of cannister 18 to assure that maximum energy is delivered to the bag 20. As is known, the closer an X-ray source is to object to be irradiated, the higher the energy delivered to the object; that is, the level of the energy delivered to the object is dependent on the distance between the two components. As is also known, the object can be irradiated faster when more energy is delivered to the object.

It is of particular importance that the irradiation received by the blood plasma in bag 20 be uniform. That is, the blood in the bag must be uniformly irradiated; that is, irradiation energy within a specified range must be provided to the blood for the same period of time to meet Federal regulations. For this purpose of providing an efficient uniform irradiation of the blood plasma bag, in the embodiment of Figs. 1-3, a second X-ray tube 17 is provided on the opposite side of the cannister 18. The X-ray tube 17 is essentially identical to X-ray tube 15 and provides energy to the opposite surface or side of the bag 20. Tube 17 is positioned the same distance from the cannister as is tube 15, that is at 23 cm from the lower surface of cannister 18. Hence, the transfusion bag 20 is

concurrently irradiated from two separate X-ray sources for a precise time.

In the embodiment of Fig. 1, the two X-ray tubes 15 and 17 are powered by the same power supply from an AC source connected through adapter 29. Two separate power sources may be provided.

It is clear from Fig. 2, that the irradiation energy from X-ray tube 17 complements the irradiation energy from X-ray tube 15. Since the energy level varies as the beam penetrates the 4cm thick bag of blood; the energy provided changes with the depth or thickness of the blood in bag 20. (As stated above, the thickness of the bags is maintained at 4 cm by the cannister.) The energy from tube 15 is maximum at the top surface of blood bag 20 and decreases as it penetrates the bag 20, and is effectively at a minimum level at the lower surface of bag 20. Conversely, the radiation energy from X-ray tube 17 is maximum at the lower surface of bag 20 and decreases to a minimum at the top surface of bag 20. The relation of the irradiation energy at any level or depth of bag 20 is a sum of the energy developed by the two tubes. In practice it has been found that irradiation of a blood plasma bag for about six minutes with the apparatus disclosed complies with Federal

regulations.

5 The blood in bag 20 becomes a factor in controlling the  
dose distribution for the irradiation. The kV, mA, time and  
filtration of the beam are carefully controlled to assure  
that the applicable dose delivered to all parts of the bag  
is similar. Transfusion bags vary in both size and  
configuration and the cannister 20 accommodates the  
different varieties while maintaining a maximum thickness of  
4 cm or less. As is known, X-ray energy is absorbed in a  
particular item as a function of density of the material and  
depth to be penetrated.

10 In the particular embodiment of Fig. 1, the energy  
level of the X-ray tubes is 160 kV. It has been found that  
to maintain uniformity of radiation to all parts of the bag,  
the tubes must provide each at least 150kV output to comply  
with the FDA specifications that the irradiation be within  
a range of 1500-2500 rads. The X-ray tubes 15 each  
irradiate the bag 20 with a surface dose of 2500rads and an  
exit dose of 1500 rads. Present requirements are that the  
bag be irradiated for a six minutes. Ideally, the  
irradiation dose effective at the center of the blood plasma  
in bag 20 is the same as the dose at the blood plasma  
adjacent the opposite (upper and lower) surfaces of the

bag.

Further, it has been found that the output port of each of the X-ray tubes 15 and 17 should preferably have a diameter to provide a 45 degree beam such that the beam has at least a diameter of 15.5 cm at 23cm distant from the tube. This permits the tubes to be placed closer to the bag, since as is known, the effective radiation is dependent on the distance of the object from the source.

It has also been found important to provide an efficient ion pump to maintain a good vacuum in the X-ray tube. An ion pump is preferred since the tube is used frequently for short periods, and hence any impurities in the vacuum can not be purged merely by usage and heating of the tube. Thus an efficient ion pump is used. In the embodiment shown the tubes both have a rating of 160 kV; however, theoretically the tubes could have different outputs rating. The 160 kV tubes are commercially available tubes with known characteristics and are manufactured by various reliable sources.

The bags 20 used in blood transfusion bags vary in both size and configuration. The cannister 18 accommodates the different varieties of bags while maintaining the bag at a maximum thickness of 4 cm or less. This insures the dose



delivered to any part of the blood will be no more than 2500  
rads and no less than 1500 rads, all per FDA specifications.  
The size of the chamber is related to the minimum width of  
the variety of blood bags to be accommodated. As depicted  
in Fig. 2, in one embodiment the dimensions of cannister are  
15.5cm x 12cm x 4 cm, and cannister contains the bag 20 in a  
snug tight position. An important concept in this  
application is that the transfusion bag 20 is held at a  
maximum thickness of 4 cm throughout.

As mentioned above, X-ray energy is absorbed in a  
particular material as a function of density and depth to be  
penetrated. As alluded to above it is important in system  
that the distance from the X-ray source 15 to the upper  
surface of bag 20 is 23 cm, and the distance to the lower  
surface of the bag 20 is 27 cm. The configuration is  
symmetrical; that is, the distance from the X-ray source 17  
to the lower surface of the bag 20 is 23 cm, and the  
distance to the upper surface of the bag 20 is 27 cm.

Fig. 5 shows an embodiment of the inventive system 11  
wherein the machine 12A includes a door 29 mounted on a  
pivot to slidably close the irradiation chamber 19. Fig. 6  
shows an embodiment of the invention wherein the machine 12  
includes a hinged door 31 with a plug 32 for closing the

irradiation chamber 19.

Fig. 4 depicts a second embodiment of the invention wherein a blood plasma bag 20 is positioned to be irradiated by a single X-ray tube 15A. In this embodiment, the plasma bag 20 is mounted in a vertical orientation, that is its longest length is vertical and its 4cm thickness is positioned vertically as contrasted to the horizontal orientation of the bag 20 shown in Figs. 1-3. A first surface or side of the plasma bag 20 is irradiated for a preselected time period. Next, rotatable support 28 rotates the bag about its vertical axis, and the opposite surface of the bag 20 irradiated for an equal period of time. The cumulative irradiation provided to the opposite surfaces or sides is thus effective to provide a uniform irradiation to the blood contained in the bag.

While the invention has been particularly shown and described with reference to a particular embodiment thereof it will be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention.